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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,938	08/21/2001	Pathiraja A. Gunatillake	1207.008US1	7489
21186	7590	03/15/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			SERGENT, RABON A	
P.O. BOX 2938			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402			1711	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,938

Applicant(s)

GUNATILLAKE ET AL.

Examiner

Rabon Sergent

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-79,81-108,111,112,117-121 and 125-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-79,81-108,111,112,117-121 and 125-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Claims 63-79, 81-103, 117-121, and 125-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Despite applicants' response, it remains unclear how the formula (I) soft segment component is to differ structurally from the chain extender of formula (I); in other words, it is not clear that the claim language allows for the respective compounds, based on formula (I), being different.

2. Applicants' response has been considered; however, it fails to clarify the issue.

Applicants have argued that the macrodiamine of the soft segment and the diamine of the chain extender may be the same and still have different properties because the hard segment is formed from the diisocyanate and diamine, whereas the soft segment comprises the macrodiamine and macrodiol. Applicants' argument is flawed. When the macrodiamine and the chain extender are the same, there will be no structural difference between the polymer linkage produced from the macrodiamine and the polymer linkage produced from the chain extender diamine. Firstly, one must realize that the macrodiamine and macrodiol will not react together to form a soft segment; these compounds and the chain extender can only form a polymer through the reaction of their respective terminal functional groups with the isocyanate groups of the diisocyanate. Therefore, the argued soft segment, derived from the macrodiamine, and the chain extender, when identical to the macrodiamine, will be identical upon reacting with the diisocyanate. There will be no difference in properties between the respective segments. Therefore, the resulting polymer will contain only linkages derived from the reaction of the diisocyanate with the macrodiol and the reaction of the diisocyanate with the macrodiamine. Within the art, the distinction between

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"hard segments" and "soft segments" is usually based on the soft segments being derived from high molecular weight monomeric or oligomeric chains and the hard segments being derived from low molecular weight monomers; however, applicants have specifically stated that the macrodiamine and the chain extender may be the same.

3. Claims 81-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Within claim 81, it is improper to define the variable, n, using "about", because it cannot be determined exactly what compounds are defined or encompassed by the structure, due to the variation or uncertainty that "about" introduces into the structure. For example, it cannot be clearly determined what value is denoted by "about 5".

It is not seen that applicants' amendment has clarified or addressed the issue.

4. Claims 125-129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate support has not been provided for the claiming of the recited degradation rankings and the cycle flex fatigue resistance values, because the values were determined using a composition that does not correspond to the composition of claim 63. The data is based on composition 2 of example 3; however, this composition has not been derived from the claimed formula (I) diamine component.

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Applicants' response is insufficient. Instant claim 63 requires that the hard segment be derived from the formula (I) diamine component; however, it is clearly stated at page 17, lines 11 and 12 of the specification that the hard segment of the polymer is not derived from the claimed formula (I) diamine component.

Furthermore, the position is taken that there is inadequate support for claiming the ranges of the degradation values, since the values are not recited as ranges, only data points within Table 5. These points are inadequate to establish that applicants were in possession of the entire range at the time of invention.

Applicants' response has been considered; however, the position is maintained that the data points within Table 5 are insufficient to provide support for the claimed ranges.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 63-79, 81-108, 111, 112, 117-121, and 125-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085).

The primary references disclose the production of polysiloxane-polyurethane (urea) polymers having enhanced biocompatibility wherein active hydrogen group containing polysiloxanes are combined with additional active hydrogen compounds, such as polyethers or polycarbonates, and the resulting mixtures are reacted with polyisocyanates to yield polymers having enhanced characteristics.

7. While Szycher et al. and JP 4-248826 disclose that amine functional polysiloxanes may be used, the references further disclose the use of hydroxyl functional polysiloxanes.

Additionally, none of the primary references disclose the specific use of an amine functional siloxane as a chain extender. However, Li et al. specifically teach the use of amine functional polysiloxane compounds, which overlap applicants' claimed soft segment and hard segment compounds, in the production of biocompatible polyureas and polyurethane ureas having improved physical and mechanical properties. Furthermore, Ohtaki et al. disclose the amino functional tetraorganodisiloxanes as modifying reactants within polyurethanes.

8. Therefore, since applicants' claimed amine functional polysiloxanes were known reaction constituents for polyurethaneurea and since they were known to bestow improved properties, including improved biocompatibility, to urethanes, it would have been *prima facie* obvious to utilize them as reactants within the compositions of the primary references, so as to arrive at the instant invention.

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9. Applicants' response is based on the argument that the claims distinguish the soft and hard segments, and it is noted that this argument is fully analogous to the argument provided in response to the 35 U.S.C. 112, second paragraph rejection, set forth within paragraph 1. However, the argument is flawed for the same reason as set forth within paragraph 2. Accordingly, the prior art rejection has been maintained.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

R. Sergent
March 8, 2004


RABON SERGENT
PRIMARY EXAMINER